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IN THE UNITED STATES DISTRICT COURT OF MONTANA
BILLINGS DIVISION

HAROLD HOLTSHOUSER, and KATHY HOLTSHOUSER, Plaintiffs, vs. UNITED STATES OF AMERICA, Defendant.	Cause No. **COMPLAINT**

1. This action arises under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq. This Court is vested with jurisdiction pursuant to 28 U.S.C. § 1346(b).

2. Plaintiffs, Harold Holtshouser ("Mr. Holtshouser") and Kathy Holsthouser ("Mrs. Holtshouser") file this Complaint against Defendant, United States of America acting through the Department of Veterans Affairs, its agents and employees.

3. Mr. and Mrs. Holtshouser have filed the appropriate SF Form 95 and sufficient time has passed since filing this form to allow for the filing of this Complaint.

4. Mr. and Mrs. Holtshouser are residents of Park County, Livingston, Montana.

5. Defendant, United States of America, through the Department of Veteran Affairs and its employees and agents, provide health care services and prescription medications to veterans.

6. Defendant provides health care and prescription medication through the VA Montana Health Care System in Ft. Harrison, Montana (VA Hospital), a community based outpatient clinic in Bozeman, Montana (VA Clinic), and a VA Pharmacy in Ft. Harrison.

7. Mr. Holtshouser is a veteran of WWII and served his country from 1942 until August of 1945.

8. Because of Mr. Holtshouser's veteran status, he received medical care and prescription medication from Defendant.

9. One of the medications that Defendant prescribed and filled for Mr. Holtshouser was metoclopramide, also known as Reglan.

10. Defendant prescribed and filled approximately 156 weeks of metoclopramide prescriptions between May 14, 2001 and March 20, 2008, to treat Gastroesophageal Reflux Disease (GERD).

11. During the time that Defendant was prescribing and filling Mr. Holtshouser's metoclopramide prescription, the FDA had restricted the duration that metoclopramide could be prescribed to patients such as Mr. Holtshouser.

12. The FDA restricted metoclopramide prescriptions for GERD to "not exceed 12 weeks in duration."

13. The FDA-approved label for GERD emphasized that metoclopramide is "indicated as short-term (4 to 12 weeks) therapy…"

14. The FDA label has a specific section about tardive dyskinesia which states: "Both the risk of developing the syndrome and the likelihood that it will

become irreversible are believed to increase with the duration of treatment and the total cumulative dose."

15. Tardive dyskinesia is the most serious and most likely adverse drug effect which results from long-term exposure to metoclopramide.

16. Tardive dyskinesia is an abnormal movement disorder that usually becomes a serious risk if the patient is exposed much beyond 12 weeks.

17. The longer the patient is exposed to metoclopramide beyond 12 weeks, the greater the risk of experiencing tardive dyskinesia and/or parkinsonism; age is also an increasing risk factor.

18. Tardive dyskinesia is typically an irreversible, painful and disabling condition.

19. Severity and irreversibility is often proportional to the cumulative length of exposure to the drug.

20. The FDA label warns that metoclopramide can also cause and/or exacerbate parkinsonism and tardive dyskinesia.

21. Mr. Holtshouser was born February 9, 1922. He was 79 years old when Defendant first prescribed and filled a metoclopramide prescription in May of 2001.

22. Mr. Holtshouser is currently 89 years old.

23. Despite the FDA restrictions and the medical literature (including VA literature) that warned and restricted metoclopramide prescriptions for periods of time longer than 12 weeks, Defendant filled approximately 156 weeks of metoclopramide prescriptions(10 mg, 4 times per day) for Mr. Holtshouser.

24. Defendant's prescribing and filling of the metoclopramide for approximately 156 weeks exceeded the FDA restriction by 1,300 percent.

25. The VA Pharmacy filled 30 day metoclopramide prescriptions for Mr. Holtshouser on: 05-15-2001, 07-27-2001, 10-02-2001, 11-20-2001, 03-12-2002, 04-12-2002, 05-09-2002, 05-29-2003, 06-18-2003, 09-18-2003, 10-14-2003, 12-08-2003, 01-06-2004, 03-04-2004, 03-30-2004, 04-19-2004, 05-12-2004, 06-08-2004, 07-13-2004,

09-01-2004, 10-28-2004, 11-23-2004, 12-23-2004, 11-06-2006, 12-04-2006, 01-04-2007, 02-08-2007, 03-14-2007, 04-12-2007, 05-07-2007, 06-11-2007, 08-06-2007, 10-11-2007, 01-16-2008, 02-27-2008, and 03-20-2008.

26. After the VA physician prescribed this medication to Mr. Holtshouser, Defendant continued to prescribe and distribute metoclopramide to him even though he was beginning to experience parkinsonism.

27. Defendant's excessive prescribing and filling of metoclopramide probably caused or aggravated Mr. Holtshouser's parkinsonism and probably caused his tardive dyskinesia.

28. Mr. Holtshouser's exposure to metoclopramide was far beyond reasonable exposure to this drug.

29. The VA Pharmacy mailed the metoclopramide to Mr. Holtshouser's home for substantially more than 12 weeks, which is far beyond that allowed pursuant to the FDA label and far beyond reasonable dosage durations for any medical condition.

30. The FDA-approved manufacturer's label for metoclopramide makes clear that the medication should not be prescribed for more than 12 weeks for any condition as do Defendant's treatment guidelines.

31. The medication that treats parkinsonism aggravates tardive dyskinesia and vice versa. In other words, it is not possible to treat one condition without making the other condition worse.

32. Every day Mr. Holthouser suffers from continuous mouth and facial pain caused by the repetitive movement of his tongue.

33. Mr. Holthouser's parkinsonism includes but is not limited to difficulty walking, balance problems, and decreased dexterity.

34. Mr. Holtshouser wakes up multiple times per night to rinse his mouth because of pain, burning and discomfort. He generally sleeps less than two hours at a time.

35. Mr. Holtshouser is depressed and tearful on a regular basis because of the pain and hopelessness of his situation.

36. He is aware that tardive dyskinesia is incurable.

37. He now understands that his treatment options are limited because he has both parkinsonism and tardive dyskinesia.

38. Mrs. Holtshouser spends substantial time and energy caring for Mr. Holtshouser every day. It is very difficult for her to watch him suffer relentlessly. She tried to keep him comfortable and consoles him regularly. She assists him in multiple ways including cooking and cleaning for him and helping him with his medication.

39. Defendant's negligence includes but is not limited to the following:

a. Exposing Mr. Holtshouser to metoclopramide far beyond a reasonable cumulative dosage;

b. Continued exposure to metoclopramide without evidence of efficacy;

c. Continued exposure to metoclopramide after it was recommended that it be stopped;

d. Prescribing and filling the metoclopramide prescription without informed consent;

e. Continued prescription and administration of metoclopramide to Mr. Holtshouser for a substantial period of time after his parkinsonism was clearly present and documented in the VA records;

f. Inadequate monitoring for parkinsonism and tardive dyskinesia;

g. Inadequate record keeping for parkinsonism and tardive dyskinesia;

h. Inadequate understanding of the risks of excessive exposure to metoclopramide and the connection between it and tardive dyskinesia and/or parkinsonism;

i. Lack of warning and/or informed consent for the patient and his family in regard to parkinsonism and tardive dyskinesia;

j. Lack of education concerning how to identify the early signs of parkinsonism and tardive dyskinesia for the patient and his family;

k. Continued dispensing of metoclopramide far beyond that allowed pursuant to the FDA label;

l. The VA Pharmacy's failure to contact Mr. Holtshouser's prescribers to discuss the excessive length of the metoclopramide prescription;

m. VA Pharmacy's failure to inform the Holtshousers of the potential risk involved with the excessive cumulative dose of metoclopramide; and

n. VA Pharmacy's failure to properly screen Mr. Holtshouser's metoclopramide prescription before it filled them in order to detect the excessive cumulative dose.

40. Defendant's negligence caused Mr. Holtshouser to suffer persistent, painful and disabling tardive dyskinesia; probably caused or aggravated parkinsonism; and, created an inability to treat his parkinsonism effectively due to the development of the tardive dyskinesia. This negligence also caused past and future damages including but not limited to lost course of life, lost household services, loss of consortium, pain and suffering, and costs associated with his related medical care.

41. Defendant's negligence caused Mrs. Holtshouser emotional suffering, lost consortium, and other related damages including but not limited to substantial time caring for Mr. Holtshouser because of his tardive dyskinesia and parkinsonism.

42. Defendant's conduct violated Montana Consumer Protection Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant for all damages recoverable under Montana law, including but not limited to:

1. All special and general damages, including economic and non-economic damages, in a reasonable sum to be proven at trial;

2. Treble damages;

3. Attorney's fees;

4. Allowable prejudgment interest;

5. Recoverable costs; and

6. Such other relief as may be just and equitable.

DATED this 30th day of September, 2011.

BIDEGARAY LAW FIRM, LLP

/s/Daniel B. Bidegaray
Daniel B. Bidegaray, Attorney
Bidegaray Law Firm, LLP
Attorney for Plaintiffs